

Testimony of Dr. Roger O. McClellan, President
Chemical Industry Institute of Toxicology
Research Triangle Park, NC
Before the Subcommittee on Health and Environment
and
Subcommittee on Oversight and Investigations
Committee on Commerce
United States House of Representatives

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Chairmen and distinguished members of the Subcommittee: I am pleased to have this opportunity to testify at your request on the scientific basis for the new National Ambient Air Quality Standards for Ozone and Particulate Matter that the Environmental Protection Agency proposes to promulgate under authority of the Clean Air Act. I request that this written testimony be included in the record as though read in its entirety.

By way of background, I serve as President of the Chemical Industry Institute of Toxicology, a not-for-profit research organization located in Research Triangle Park, North Carolina. The Institute is supported principally by some 30 leading industrial firms and has a mission of developing, through the conduct of research, an improved scientific basis for understanding and assessing the human health risks of exposure to chemicals. This mission is being achieved through the conduct of an in-house research program carried out by 160 scientists, postdoctoral fellows, and supporting personnel.

The comments I offer are based on my experience as a scientist concerned with the risks of airborne materials and my extensive service in advisory roles to numerous public and private organizations. (An abbreviated biographical sketch is appended.) My advisory experience has included long-term service on the EPA Science Advisory Board. I have served under each of the Agency's Administrators on a number of Committees, previously as Chair of its Clean Air Scientific Advisory Committee (1988 to 1992), Environmental Health Committee, Environmental Radiation Exposure Advisory Committee, and the Research Strategies Advisory Committee and as a member of the Relative Risk Reduction Strategies Committee. Most recently, I have served as a member of the Clean Air Scientific Advisory Committee Panels considering the National Ambient Air Quality Standards for Ozone and Particulate Material. I also served on the CASAC panels that earlier reviewed the scientific basis for the current National Ambient Air Quality Standards for ozone and particulate matter.

Roger O. McClellan

Summary Points

Ozone

- There is no threshold for onset of biological responses and, thus there is no “bright line” to distinguish between any of the possible standards.
- The level at which the ozone standard is set is a policy call.
- I would recommend 90 ppb, 8-hour averaging time and use of a 3-year average of third highest maximum 8-hour average ozone.

Particulate Matter

- The health effects of PM are difficult to separate from those of other pollutants because of the high degree of correlation between concentrations of the several pollutants.
- The data base on PM₁₀ has increased substantially during the last decade and justify its continued use as a PM indicator.
- Limited data on PM_{2.5} suggest it may be a useful indicator.
- EPA has “rushed to judgment” in proposing a new PM_{2.5} standard.
- The nature of the exposure-response relationship at exposure levels in the range of the proposed PM_{2.5} standard are highly uncertain.
- Knowledge of the mechanisms of possible action of PM_{2.5} and of a mechanistic linkage from sources of PM to exposure to response is highly uncertain raising questions as to whether establishment of a PM_{2.5} standard will have positive health benefits.
- I favor reaffirmation of the PM₁₀ standard and a 5-year delay in selecting a new PM indicator. During this time period data could be generated to provide a basis for a scientifically defensible new PM NAAQS.

The Clean Air Act and Criteria Pollutants

Put in its simplest form, the Clean Air Act requires the Administrator to develop criteria and promulgate standards for certain air pollutants to protect against adverse effects in the public, including sensitive populations, with an adequate margin of safety. As clearly implied by the statutory language, levels of pollutant exposures can be identified that cause effects, while lower levels of exposure will be without effect (i.e., a threshold for response). A "margin of safety" is then used to select a lower level for the standard, a level that, if attained, should not result in unacceptable risk.

Ozone Standard

The current primary NAAQS for ozone is set at 0.120 ppm with a one-hour averaging time. Attainment of the standard occurs when the expected number of days per calendar year with a maximum hourly average concentration greater than 0.120 is equal or less than one. Operationally, the standard is exceeded if the 0.120 ppm hourly average concentration is exceeded a fourth time in a three-year period.

In 1993, the EPA Administrator reaffirmed the 0.120 ppm standard with a one-hour averaging time. At the same time, the Agency initiated the preparation of an updated criteria document on ozone and made plans for preparation of a staff paper for CASAC review of both the criteria document and staff paper. The CASAC came to closure on the criteria document on November 28, 1995 and on the staff paper on November 30, 1995.

The review process for the NAAQS for ozone considered a substantial amount of new data published since the last CASAC review was concluded in early 1989. The data came from four sources; controlled human exposure studies, field studies of children and healthy adults, analysis of air quality data and hospital admissions and laboratory animal studies.

The controlled human exposure studies involved individuals engaged in light to heavy exercise with exposure to ozone over a range of concentrations for 1 to 6.6 hr. Decrements in pulmonary function and increases in symptoms of respiratory responses were exposure concentration and exposure duration dependent. However, there was substantial intergroup variability in response as well interindividual variability for repeated exposures. The results of these studies support the use of an 8-hour averaging time.

The field studies of children in summer camp and exercising adults took advantage of naturally occurring variations in ambient ozone concentrations. Lung function tests were performed in all the individuals. A small, but substantially significant, association between ozone concentrations and reduced pulmonary function was observed for both groups. The relationship between increased ozone and decreased function was approximately linear with no clear threshold for an absence of effect.

The hospital admission studies examined the association between daily ozone concentrations and daily hospital admissions for respiratory effects. Asthmatics were identified as one susceptible subpopulation. Linear relationships were observed with increasing ozone and increased admissions with no clear evidence of a threshold.

The animals studied revealed effects that were qualitatively similar to those seen in people. The results of a key study with rats and mice exposed 5 days per week to ozone at exposure levels of 0.12 ppm and higher for 2 years suggested that long-term exposure at current ambient concentrations of ozone were unlikely to produce serious, irreversible changes in the lungs. I found those findings reassuring; they reduced my concern for the long-term impact from brief exposures that produce reversible effects. Based on consideration of all of the data, the EPA staff paper recommended consideration of an 8-hour averaging time standard in the range of 0.070 to 0.090 ppm and a potential for multiple exceedances.

Based on the information presented in the ozone criteria document and analyzed in the ozone staff paper, the CASAC reached several key conclusions:

- (1) Ozone remains an appropriate indicator of photochemical oxidants,
- (2) An 8-hour averaging time standard is more appropriate for a human health-based standard than a 1-hour average time,
- (3) “The weight of the evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure above background concentrations” and, thus, “there is no ‘bright line’ which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health.”
- (4) The CASAC Ozone Panel members expressed a range of preferences for the level of the standard.

<u>Number of Panel Members</u>	<u>Preferred Ozone Level (ppm)</u>
1	0.090 – 0.100
3	0.090
1	0.080 – 0.090
3	0.080
2	Policy Call

It is my professional judgment that the primary ozone standard should be set at 0.090 ppm with an 8-hour averaging time and the use of the 3-year average of the annual third highest maximum of 8-hour average ozone concentration to evaluate attainment of the standard. I would personally prefer to have some form of averaging of data from multiple monitoring sites, when available, rather than using the highest monitor to determine attainment of the standard. The use of multiple monitors would better reflect population exposure and aggregate public health risk.

My professional opinion on the level and form of the ozone standard was shaped by consideration of data such as that shown in Table 1. This table is based on a study by Thurston et al. (1992) who examined the relationship between ozone levels and hospital admissions. The model assumed ozone effects down to a background level of 0.040 ppm. The columns in the table represent various ozone control scenarios compared to the present “as is” situation (the far right column). The far left column represents the situation if the present ozone standard were attained. The first row on the table (Excess Admissions) was prepared by the EPA staff and

included in the draft Ozone Staff Paper. It may be noted that the excess admissions for various ozone control scenarios included 210 cases for the present standard to a range of 60 to 240 cases for alternative standards. For comparison the present situation ("as is") is estimated to result in about 400 cases. The five lower rows in the table were prepared by CASAC Panel members. The second row reporting the excess admissions as a percentage change from the present standard at first glance appears to suggest considerable difference between the several options. However, the other rows are worthy of detailed consideration before a final conclusion is drawn.

The third row includes both the excess admissions due to ozone-aggravated asthma above the level of the standard and those cases related to ozone below the level of the standard down to background. The relative effect of the different options now appears to be much less, as seen from examining row 4. Let us now turn our attention to row 5, all asthma admissions, with a baseline of approximately 30,000 cases. When this value is compared with that for the various options, ozone-aggravated asthma admissions clearly represent only a small fraction of the total number of cases and the difference in impact of the various options for the ozone standard is small.

It is especially important to note that 680 asthma admissions per year are attributed to background levels of ozone which is assumed to be 0.040 ppm of ozone. These calculated cases are a reflection of the linear exposure-response models used to calculate the ozone attributable cases.

The primary public health issue relates to the approximately 30,000 cases of asthma admissions. I can personally identify with these cases since one of my children, who grew up in the clean air of New Mexico, was and is an asthmatic. My firsthand recollection of his suffering from asthma attacks triggered by multiple causes such as animal dander, grass pollens, extreme cold air, and heavy exercise left an imprint on me. As much as anyone, I would like to better understand what causes asthma including the vexing issue of why asthma rates are increasing especially when air quality is improving. I have serious reservations as to the extent to which ozone exposures are a significant contributor to the asthma problem.

Let me hasten to add that the health impacts of ozone are not restricted to effects in asthmatics. However, the table clearly illustrates the importance of considering the estimated impacts of pollutant exposures within the broader context of other risk factors for specific health outcomes. In my opinion, the ultimate concern of society is for the aggregate risks from all causes and how best to achieve an overall reduction.

I am personally a strong advocate of comparative risk analyses such as detailed above to help guide decisions on important societal issues. It is my understanding that the EPA Administrator can use analyses such as this in making decisions on the ozone standard although the Administrator is prohibited from explicitly considering costs of implementing the standard.

Before leaving the ozone issue, let me note that I believe it is unfortunate that the Clean Air Act prohibits the consideration of cost in setting the standard. In my opinion, the best interests of society would be served if attention could be focused on the "best buy" for societal actions that

will reduce health risks, including those of ozone. Further reductions in ozone may not be cost-effective relative to other options for reducing risks and improving health.

The explicit consideration of the cost of achieving the various options would be of substantial value in making a decision that is likely to have a multibillion-dollar impact on society.

Particulate Matter

The current particulate matter standard was promulgated in 1987 when the indicator for particles was changed from Total Suspended Particles (TSP) to PM₁₀, the latter referring to particles with a mean aerodynamic diameter less than 10 μm . The 24-hour PM₁₀ standard was set at 150 $\mu\text{g}/\text{m}^3$, with no more than one expected exceedance per year, and the annual PM₁₀ standard set at 50 $\mu\text{g}/\text{m}^3$, expected arithmetic mean. The PM₁₀ standard is thought to provide a more health-protection-relevant metric for controlling exposure than the old TSP metric since it is based on measuring the fraction of PM most likely to be inhaled and deposited.

The particulate matter National Ambient Air Quality Standard for Particulate Matter is not chemical specific unlike the chemical specific standards for other criteria pollutants and most other substances regulated by the Environmental Protection Agency. The PM standard applies to a broad class of chemically and physically diverse substances that exist as discrete particles (liquid droplets or solids) over a wide range of sizes. PM is characterized as to its mass within a given size range.

Knowledge of the size and origin of particles is, fundamental to understanding their potential health effects and, ultimately, the establishment of appropriate standards and control strategies. Particles in the atmosphere vary widely as to their size and origin. The smallest particles arise from condensation of vapor and a clustering of individual molecules. These very fine particles grow in size and coagulate in the atmosphere to form fine (or accumulation mode) particles that are typically less than a micrometer in diameter. Other larger or coarse particles typically arise by mechanical processes such as the erosion of soil.

The size of particles influences the dynamics of particles in the atmosphere. The finest particles coagulate to become larger particles. These particles may be removed from the atmosphere by rain. The largest particles may settle out due to gravity. Small and medium size particles may be transported long distance by the wind. As a former resident of Albuquerque, New Mexico, I can recall that in the spring we sometimes had some of Arizona blow through when the winds were from the west and Texas and Oklahoma blow through when the winds were from the east.

Scientists studying particles in the atmosphere have appreciated the need to better understand particle size and this has led to the development of methods for collecting particles and characterizing the particles as to size. Just as size influences how particles behave in the atmosphere, size also influences their potential for being inhaled, deposited in the respiratory tract and causing adverse health effects. The concern for how particles of different sizes could affect health also influenced the design of air sampling devices.

Some of the conventions for characterizing particles as to their size are illustrated in Figure 1.

In particular, note the size fractions designated as (1) Total Suspended Particulates (TSP); (2) Particulate Matter, 10 microns size (PM₁₀); and (3) Particulate Matter, 2.5 micron size (PM_{2.5}).

The TSP sample represents essentially all the particles that can be drawn into a high volume sampler. This includes many large, heavy particles that have a very low probability of being inhaled and reaching the lungs. These particles are clearly a nuisance but are not of major health concern.

Recognition that smaller particles that can be inhaled led to the development of methods for collecting smaller particles including the PM₁₀ fraction. These are collected with devices that will collect 50% of the particles 10 micrometers in aerodynamic diameter. Particles larger than 10 micrometers are collected less efficiently, smaller particles are collected more efficiently. The PM_{2.5} fraction is similar except the cut-off is set at 2.5 micrometers. As an aside, it should be noted that some of the smallest of the coarse mode particles are collected in the PM_{2.5} sample.

In 1979-1980 EPA was struggling with the issue of developing a size-selective PM NAAQS to replace the TSP standard set in 1971. Several different size cuts were under consideration and there was a flurry of activity to gather field data using new devices including some calibrated for PM₁₅, PM₁₀, and PM_{2.5}. However, the debate was largely removed from EPA's regulatory agency in 1981 when the International Standards Organization adopted a 10 micrometer cut point for particles that could penetrate to the human thorax (i.e., the trachea, conducting, and pulmonary airways). This focused attention on a PM₁₀ standard which was formally promulgated in 1987. With promulgation of the of the new standard and the need to demonstrate regulatory compliance, there was a general shift to PM₁₀ measurements. TSP measurements were discontinued and, unfortunately, so were most measurements of PM_{2.5}. I have termed this phenomena "looking under the regulatory lamppost." In general, after closure on the PM criteria document and staff paper in 1986, the level of financial support for research on PM dwindled.

In my opinion, the Agency took appropriate action to move to a PM₁₀ indicator in 1987. The use of the PM₁₀ indicator has been effective in guiding actions to control particulate air pollution and minimize the likelihood of adverse health effects attributable to particulate air pollution. From 1988 to 1995 there has been a 22% reduction in the annual mean PM₁₀ concentrations (see the EPA National Air Quality and Emissions Trends Report, 1995). This and a companion document, National Air Pollutant Emission Trends, 1990-1994 are excellent references for gaining an appreciation of the substantial progress being made in improving air quality in the United States. Unfortunately, detailed data are not available on trends in PM_{2.5} and PM_{1.0} measurements. However, I suspect substantial reductions have also occurred in the concentrations of these smaller particles.

During the early 1990s reports begun to appear in the literature of time series analyses of PM measurements and daily mortality. These were retrospective, opportunistic studies of data collected for other purposes. These studies frequently used techniques developed originally for econometric analyses. The techniques used attempted to account for or filter out effects such as season of year, temperature, etc., that could influence mortality with the remaining statistical

relationship between daily PM and daily mortality quantified. Later studies attempted to take account of the role of other pollutants such as ozone and acid sulfates. A major handicap to the conduct of many of these studies was the lack of PM₁₀ data. In many cases, the best available data were for TSP. These were then converted or extrapolated to PM₁₀ values or, in some cases, even extrapolated to PM_{2.5} values. On average the investigators found about a 4% increase in daily mortality for a 50 µg/m³ increase in PM₁₀ concentration or extrapolated PM₁₀ values.

Unfortunately, only a very few long-term prospective studies of cohorts of individuals have been conducted with associated measurements of PM and other pollutants. Only rarely have long-term multiyear studies been conducted with research quality air pollution measurements made rather than depending on regulatory compliance measurements. The result is excessive dependence on the old TSP measurements or more recently PM₁₀ measurements. Only very limited research has been done when both PM₁₀ and PM_{2.5} have been measured and only very recently have some PM_{1.0} measurements been obtained. In the cohort studies mortality rates after adjustment for smoking and other confounding variables have been related to the PM₁₀ or PM_{2.5} measurements or extrapolated values. EPA used the mortality estimates from two such prospective studies to conclude that there are premature deaths due to chronic exposure to PM.

In my opinion, the EPA staff and consulting scientists assisting the Agency did an admirable job of compiling in a very short period of time all that is currently known about the health effects of PM. Unfortunately, the price must now be paid for inadequate support of research on the effects of air pollution. The data base available today is not sufficient to establish a new PM indicator, nor select the level and form of a new standard.

The data suggest that high levels of PM as experienced in the past are associated with increased morbidity and mortality. However, I must note that some investigators have suggested that the effect measured is a general air pollution effect with PM measurements serving as a surrogate measure of air pollution rather than as a causative agent. The data are reasonably strong for PM₁₀. Unfortunately, the dearth of PM_{2.5} measurements serve as a serious obstacle to rigorously evaluating the association between PM_{2.5} and multiple measures of health for specific populations including those that might be especially susceptible. And we have no evaluations of possible association between various health indices and other PM metrics such as PM_{1.0} (that would more accurately reflect particles that have been recently formed) or particle size and chemical specific metrics traceable to specific types of sources. An absence of data on other plausible alternatives and the bright light of the regulatory lamppost keeps drawing us back to evaluating associations with PM₁₀ and to a lesser extent, PM_{2.5}. It has been argued that the only way to get funding for more PM_{2.5} measurements is to get a PM_{2.5} standard. Thus, we are faced with the perverse situation of creating a standard to get scientific data rather than having a standard developed based on solid scientific data. Limited data recently obtained on PM₁₀, PM_{2.5}, and PM_{1.0} size fractions suggest that EPA may be making a serious error in proposing a PM_{2.5} standard to control health risks related to fine particles. In the western United States where PM_{2.5} measurements include substantial soil dust, the use of a PM_{2.5} indicator may lead to exaggerated estimates of risk. These data strongly suggest that a PM_{1.0} indicator may be more appropriate than the use of a PM_{2.5} indicator.

During the recent PM review, the serious shortcomings in the scientific data on PM_{2.5} and on PM_{1.0} led me to not support the promulgation of either an annual or a 24-hour PM_{2.5} standard. I did support reaffirming the present PM₁₀ standard only using a more robust statistical form. I reluctantly noted that if EPA was going to propose a PM_{2.5} standard, I would set the 24-hour standard at 75 µg/m³ and an annual standard at 25 µg/m³. These would represent levels that would likely not result in misdirected control strategies while PM_{2.5}, and hopefully also other PM metrics are measured throughout the country. A national strategy to better characterize PM air quality would also provide the groundwork for development of a cost-effective PM control strategy. And, most importantly, there is an urgent need to initiate multiple long-term prospective epidemiologic studies to assess if there is currently a PM problem and, if so, what specific size or chemical fractions are responsible. There is an urgent need for research to establish a mechanism-based causal linkage between PM fractions to be regulated and human disease.

To address research needs such as I have outlined in general terms will require expenditures on the order of \$50 million per year for five years compared to the less than \$20 million EPA is expending on PM research in 1997. The alternative to making the research investments and acquiring information for a science-based standard is to proceed blindly with development of standards that will have a multibillion dollar impact and may or may not impact positively on human health. I urge Congress to provide EPA guidance for immediately initiating the expanded research program needed to establish science-based NAAQS for PM.

Reference

Thurston, G.D., Ito, K., Kinney, P.L., and Lippmann, M. (1992). A multi-year study of air pollution and respiratory hospital admissions in three New York State metropolitan areas: results for 1988 and 1989 summers. *J. Exposure Anal. Environ. Epidemiol.* 2:429–450.

TABLE 1: ESTIMATED HOSPITAL ADMISSIONS FOR ASTHMATICS IN THE NEW YORK CITY AREA
FOR VARIOUS OZONE CONTROL SCENARIOS

Row		1H1EX* 0.12	1H1EX 0.10	8H1EX 0.10	8H1EX 0.09	8H1EX 0.08	8H1EX 0.07	8H5EX 0.09	8H5EX 0.08	AS IS
1	Excess Admissions ^a	210	130	240	180	110	60	180	120	≈385 ^d
2	% Δ from present standard	0%	-38%	+14%	-14%	-48%	-71%	-14%	-42%	+83%
3	Excess + background ^b	890	810	920	860	790	740	860	800	1065 ^e
4	% Δ from present standard	0%	-9%	+3%	-3%	-11%	-17%	-3%	-10%	+20%
5	All Asthma Admissions ^c	28,295	28,215	28,325	28,265	28,195	28,145	28,265	28,205	28,470 ^f
6	% Δ from present standard	0%	-0.3%	+0.1%	-0.1%	-0.4%	-0.5%	-0.1%	-0.3%	+0.6%

*1H1EX - 1 hour averaging time, 1 exceedance

a - excess asthma admissions attributed to ozone levels exceeding a background concentrations of 0.04 ppm; from Table VI-2, page 155 in the August 1995 OAQPS Draft Staff Paper

b - asthma admissions included in (a) plus those due to background ozone concentrations; admissions due to background = $1065^e - 385^d = 680$

c - asthma admissions due to all causes = $28,470^f - 385^d + \text{Excess Admissions from row 1}$

d - estimated from Figure V-15, page 125 in the August 1995 OAQPS Draft Staff Paper

e - from page 127, line 13 in the August 1995 OAQPS Draft Staff Paper

f - total admissions from asthma = total asthmatics (365,000 - from page 126, line 24) x hospitalization rate (78/1000 asthmatics - from page 126, line 29)

Adapted by the Clean Air Scientific Advisory Committee Ozone Panel from the EPA Ozone Staff Paper. The notations in the footnote above refer to the August 1995 OAQPS Draft Ozone Staff Paper

BIOGRAPHY

ROGER O. McCLELLAN, D.V.M. serves as President of the Chemical Industry Institute of Toxicology, a position held since September 1988. The CIIT is supported by dues payments from some 40 leading industrial firms and has a mission of creating an improved knowledge base for understanding and assessing the adverse effects of exposure to chemicals. Prior to his appointment as President of CIIT, Dr. McClellan was Director of the Inhalation Toxicology Research Institute, and President and Chief Executive Officer of the Lovelace Biomedical and Environmental Research Institute, Albuquerque, New Mexico. He began his career with Lovelace in 1966, serving as Director, Fission Product Inhalation Program (1966-1973), and later as Vice President and Director, Inhalation Toxicology Research Institute, Lovelace Foundation for Medical Education and Research (1973-1976). During his 22 years with the Lovelace organization, he provided leadership for development of one of the world's leading research programs concerned with the toxic effects of airborne materials. Prior to joining the Lovelace organization, he was a scientist with the Division of Biology and Medicine, U.S. Atomic Energy Commission, Washington, DC (1965-1966), and Hanford Laboratories, General Electric Company, Richland, WA (1959-1964). He received his Doctor of Veterinary Medicine degree from Washington State University in 1960.

Dr. McClellan has served in an advisory role to numerous public and private organizations. He is past Chairman of the Clean Air Scientific Advisory Committee, Environmental Health Committee, Research Strategies Advisory Committee, and Member of the Executive Committee, Science Advisory Board, U. S. Environmental Protection Agency; Member, National Council on Radiation Protection and Measurements; Member, Advisory Council for Center for Risk Management, Resources for the Future; a former Member, Health Research Committee, Health Effects Institute; and service on National Academy of Sciences/National Research Council Committee on Toxicology, Committee on Risk Assessment for Hazardous Air Pollutants, and Committee on Health Risks of Exposure to Radon. He also serves as Adjunct Professor at Duke University, University of North Carolina - Chapel Hill, North Carolina State University, University of New Mexico, and Washington State University. He is active in the affairs of a number of professional organizations, including past service as President of the Society of Toxicology and the American Association for Aerosol Research. He serves in an editorial role for a number of journals, including service as Editor of CRC Critical Reviews in Toxicology. He is a diplomate of the American Board of Toxicology and the American Board of Veterinary Toxicology.

Dr. McClellan's contributions have been recognized by receipt of a number of honors, including election to membership in the Institute of Medicine of the National Academy of Sciences. He is a Fellow of the Society for Risk Analysis. He has a long-standing interest in environmental and occupational health issues, especially those involving risk assessment and air pollution, and in the management of multidisciplinary research organizations. He is a strong advocate

of risk-based decision-making and the need to integrate data from epidemiological, controlled clinical, laboratory animal and cell studies to assess human health risks of exposure to toxic materials. Most recently, he served as a member of the EPA Clean Air Scientific Advisory Committee Review Panel for criteria documents and staff papers on ozone and particulate material.